With regard to U.S. Patent No. 5,478,577, the Examiner states "though the claims do not contain the statements (i) and (ii) (see pg. 2 of response filed 1/28/02), 5,478,577 and the instant Application claim the same controlled-release oral dosage form." Therefore, the Examiner concludes that the "controlled-release oral dosage form of 5,478,577 and the instant invention must have the same properties."

This rejection is traversed. It is respectfully submitted that the present claims and the claims of U.S. Patent No. 5,478,577 do not claim the same controlled-release oral dosage form as alleged by the Examiner. With regard to U.S. Patent No. 5,475,577, it is again respectfully submitted that the claims of this patent fail, at the very least, to recite or suggest the following limitations of independent claim 6 of the present application:

> *(i)...wherein the dissolution rate in-vitro of the dosage form, when measured by the USP Paddle Method of U.S. Pharmacopeia XXII (1990) at 100 rpm at 900 ml aqueous buffer at pH 1.6 and 7.2 and at 37°C is from about 12.5% to about 42.5% (by wt) opioid released after 1 hour, from about 25% to about 65% (by wt) opioid released after 2 hours, from about 45% to about 85% (by wt) opioid released after 4 hours and greater than 60% (by wt) opioid released after 8 hours,...*
>
> *(ii)...the in-vitro release rate being substantially independent of pH in that a difference, at any given time, between an amount of opioid released at one pH and an amount released at any other pH, when measured in-vitro using the USP Paddle Method of U.S. Pharmacopeia XXII (1990) at 100 rpm in 900 ml aqueous buffer is no greater than 10%,....*

In an obviousness-type double patenting rejection, although the disclosure of a patent may not be used as prior art, the specification can always be used as a dictionary to learn the meaning of a term in the patent claim, or those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claim in the patent. See M.P.E.P. § 804 (8th Edition). Therefore, even assuming it is necessary to look to the specification of U.S. Patent No. 5,478,577 in view of the claims recited therein, the in-vitro dissolution rates

mentioned therein do not teach, hint or suggest the in-vitro dissolution rate of claim 6 of the present invention.

With respect to Application No. 09/390,719 (now issued as U.S. Patent No. 6,294,195 on September 25, 2001) and U.S. Application No. 08/938,898 (abandoned in favor of U.S. Application No. 10/162,132) and U.S. Application No. 09/304,694, it is respectfully submitted that the claims of this patent and applications fail at the very least, to teach, hint, or suggest the following limitations of independent claim 6 of the present application:

> *(i)...wherein the dissolution rate in-vitro of the dosage form, when measured by the USP Paddle Method of U.S. Pharmacopeia XXII (1990) at 100 rpm at 900 ml aqueous buffer at pH 1.6 and 7.2 and at 37°C is from about 12.5% to about 42.5% (by wt) opioid released after 1 hour, from about 25% to about 65% (by wt) opioid released after 2 hours, from about 45% to about 85% (by wt) opioid released after 4 hours and greater than 60% (by wt) opioid released after 8 hours,...*
>
> *(ii)...the in-vitro release rate being substantially independent of pH in that a difference, at any given time, between an amount of opioid released at one pH and an amount released at any other pH, when measured in-vitro using the USP Paddle Method of U.S. Pharmacopeia XXII (1990) at 100 rpm in 900 ml aqueous buffer is no greater than 10%,....*

On this basis, Applicants respectfully request that all of the Examiner's double patenting rejections be withdrawn.

Applicants further point out to the Examiner that in the previous Office Action, the pending claims were provisionally rejected over U.S. Patent Application No. 09/632,718 under obviousness-type double patenting. In the current Office Action, this application was not mentioned by the Examiner with respect to obviousness double patenting rejection.

II. Rejections under 35 U.S.C. §102

Claims 6-15, and 18-19 were again rejected under 35 U.S.C. § 102(e) "as being unpatentable over Paradissis et al. (5,133,974)." The Examiner has rejected claims 6-15 and 18-19 "for the reasons set forth in the Office Action mailed October 12, 2001, Paper No. 9, and those found below."

In stating that Applicants' previous argument was unpersuasive, the Examiner "directs Applicant to claim 2 of the reference, wherein narcotics are disclosed as drugs for use in the invention", and "points out that morphine, oxycodone and hydromorphone are defined in as narcotics in the reference." "In regard to pharmacokinetic parameters, the Examiner respectfully points out that since the opioid analgesic contained in a controlled-release matrix of the reference is the same as that of the instant invention, then the opioid analgesic contained in a controlled-release matrix would have to have the same pharmacokinetic parameters."

This rejection is respectfully traversed as Paradissis et al. does not disclose opioids contained in a controlled release matrix. To the contrary, Paradissis et al. comprises an extended release particle comprising an immediate release particle coated with a dissolution modifying system containing plasticizers and a film forming agent (*See, e.g.*, column 6, lines 19-33) and it is submitted that there is no teaching, hint or suggestion in Paradissis et al. of an "opioid analgesic being contained in a controlled-release matrix" as recited in claim 6. Further, Paradissis et al. fail to teach, hint or suggest a dosage form having an "in-vitro release rate being substantially independent of pH in that a difference, at any given time, between an amount of opioid released at one pH and an amount released at any other pH, when measured in-vitro using the USP Paddle Method of U.S. Pharmacopeia XXII (1990) at 100 rpm in 900 ml aqueous buffer is no greater than 10%".

Even assuming arguendo that the present claims did recite an opioid analgesic coated with a controlled release coating, it is respectfully submitted that such claims would be patentable over the Paradissis reference. The Examiner has failed to provide a basis in fact and/or technical reasoning to reasonably support the determination that the alleged inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. And Inter. 1990) (emphasis in original).

In view of the above, it is respectfully requested that all of the Examiner's 35 U.S.C. §102(e) rejection over Paradissis et al. be withdrawn.

III. Conclusion

It is now believed that the above-referenced rejections have been obviated and it is respectfully requested that the rejections be withdrawn. It is believed that all pending claims are now in condition for allowance.

The Examiner is invited to contact the undersigned at the telephone number provided below if it is determined that any further issues remain.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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